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| 10/564,745 | 05/11/2006 | Hiroshi Takayama | 023312-0120 | 1476 |

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| EXAMINER | |
|---|---|
| SZPERKA, MICHAEL EDWARD | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/564,745 | TAKAYAMA ET AL. | |
| | Examiner | Art Unit | |
| | Michael Szperka | 1644 | |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☒ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response and amendments received December 4, 2008 are acknowledged.

Claims 1-11 have been canceled.

Claims 12-19 have been added.

Claims 12-19 are under examination in this office action as they read on antibodies that bind human glycoprotein VI (GPVI).

2. Applicant's response received December 4, 2008 has cancelled all previously pending claims in favor of presenting new claims. As such all prior grounds of rejection have been rendered moot.

Upon consideration of the newly presented claims, the following new grounds of rejection are set forth.

*Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Smethurst et al. (WO 03/054020, of record) as evidenced by Janeway et al. (chapter 3 of Immunobiology, 3rd edition, 1997).

Smethurst et al. disclose human antibodies that bind human GPVI as well as pharmaceutical compositions comprising said antibodies (see entire document,

particularly the title, abstract, pages 4-5 and 38-40, and claims 1-14). Such antibodies are disclosed for use in treating numerous diseases and disorders characterized by unwanted platelet aggregation, and that said antibodies are disclosed as inhibiting collagen-induced aggregation (see particularly pages 6-8 and claims 6, 7, and 22-35).

Therefore, the prior art anticipates the claimed invention.

Applicant's arguments filed December 4, 2008 have been fully considered but they are not persuasive. Applicant argues that the antibodies of Smethurst et al. are not disclosed as consisting of two heavy and two light chains, and that therefore the disclosure of Smethurst et al. does not anticipate the claimed invention.

This argument is not persuasive because it is well known in the art that antibodies are heterodimers consisting of two identical heavy chains and two identical light chains covalently joined by disulfide bonds as is evidenced by Janeway et al. (see entire chapter, particularly section 3-1 and Figure 3.1). Smethurst et al. disclose that their antibodies include whole antibody molecules that have two heavy and two light chains (see particularly pages 24-26, 34, 37, and 38).

Therefore, the prior art anticipates the claimed invention.

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qian et al. (of record as reference B6 on the 12/14/07 IDS) in view of Kipriyanov et al. (Molecular Biotechnology, 1999, 12:173-201).

Qian et al. disclose human single chain Fv antibodies that bind human GPVI and their use in pharmaceutical compositions that comprise said antibodies (see entire document, particularly the abstract and Figures 1-5). Their antibodies are disclosed as inhibiting collagen-induced aggregation (see particularly Figure 5). These antibodies differ from the instant claimed antibodies in that the scFv of Qian et al. are not divalent molecules comprising two heavy and two light chains.

Kipriyanov et al. disclose that the routine recombinant production of antibodies allows for the production of molecules wherein antigen binding and effector domains can be altered at will based upon the needs of the artisan, and indicates that whole antibodies have the advantage of comprising an Fc domain which confers various types of immune activity based upon the chosen Fc domain and that whole antibodies comprise a longer half-life in vivo due to the presence of the Fc domain as compared to scFv antibodies.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the scFv of Qian into whole antibodies to gain the advantages of effector function and greater longevity disclosed by Kipriyanov et al. and would have a reasonable expectation of success in doing so because of the routine nature of structurally rearranging immunoglobulin molecules using recombinant means as disclosed by Kipriyanov et al.

*Double Patenting*

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 12-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13, 20-22, and 24 of copending Application No. 11/816,233. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims anticipate the breadth of the instant claims in that the copending claims recite additional functional limitations and specific amino acid sequences by SEQ ID number for antibodies that bind human GPVI.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has acknowledged the potential for overlapping subject matter between the instant and copending claims and has asked that this rejection be held in abeyance until all other rejection have been overcome in the instant application.

Since applicant has not amended the claims, canceled claims, or filed a terminal disclaimer concerning the copending claims the provisional rejection is maintained.

9. Claims 12-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-45, 57, and

58 of copending Application No. 11/912,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims anticipate the breadth of the instant claims in that the copending claims recite additional functional limitations and specific amino acid sequences by SEQ ID number for antibodies that bind human GPVI.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has acknowledged the potential for overlapping subject matter between the instant and copending claims and has asked that this rejection be held in abeyance until all other rejection have been overcome in the instant application.

Since applicant has not amended the claims, canceled claims, or filed a terminal disclaimer concerning the copending claims the provisional rejection is maintained.

10. No claims are allowable.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Primary Examiner
Art Unit 1644

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